REMARKS

The following remarks are submitted as a full and complete response to the Office Action issued on July 5, 2006. Claims 1-16 are pending in this Application.

Applicants respectfully request the favorable reconsideration of the application.

Rejection under 35 U.S.C. §103(a)

The Office maintains the rejection of claims 1-16 as obvious over Taketoshi. Applicants respectfully traverse this rejection.

The Office's rejection seems to be based on the following reasoning:

(1) The bonding in the Taketoshi composition must be the same as that in the claimed hybrid. The Office reasoned that while an amine group of itaconazol is used in forming a bond in the claimed hybrid, Taketoshi discloses drugs with amino groups as suitable for intercalation;

(2) Applicants' own method places cationic ions such as Na+ or Ca2+ between the layers, which, Applicants argued, prevents the formation of ionic bonding in the Taketoshi method;

(3) It would have been obvious to one of ordinary skill in the art to substitute one cationic ion with another cationic ion such as H+; and

(4) The method for making the claimed hybrid is the same as that disclosed in Taketoshi.

Applicants respectfully disagree with the Office's reasoning in maintaining the rejection. In particular, Applicants note that the reasoning (4) is not correct. In the claimed method, a layered silicate and a drug are separately dispersed or dissolved in an aqueous solution and in an organic solvent, respectively, and then the aqueous solution containing the layered silicate and the organic solvent containing drug are mixed. *See* Claim 5. In contrast, according to paragraph [0007] of Taketoshi, both a drug and a layered silicate are mixed together in an aqueous solution containing aqueous organic solvent, without steps for dispersing or dissolving layered silicates and a drug in a suitable solvent separately. Without these pre-steps, interlayer cations of the layered silicates cannot be substituted with hydrogen ions which are required for ionic bonds to be formed between the drug and the layered silicates. As explained in the specification at paragraph [0027] of the present application, "the present invention enables a drug of interest with no charge such as itaconazole to proceed intercalation/adsorption by substituting the interlayer cations of the layered silicates with hydrogen ions before the intercalation/adsorption of step (3) since the intercalation/adsorption does not occur between the drug of interest with no charge and the layered silicates. As a result, Taketoshi fails to teach a step for existing cations to be replaced with hydrogen ions which is required to form an ionic bond between the drug and the layered silicates.

Consequently, the composition disclosed in Taketoshi cannot have an ionic bond between the drugs and the layered silicates. Office's argument (1) simply derives from the misunderstanding that the method for making the claimed hybrid is the same as that

disclosed in Taketoshi. Therefore, Applicants respectfully submit that the Office's reasoning (1) is also incorrect.

With respect to the Office's reasoning (2), Applicants respectfully submit that this reasoning is not relevant to the current claims since the current claims are explicitly limited to hybrids wherein interlayer cations of the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug.

With respect to the reasoning (3), Taketoshi fails to teach or suggest that interlayer cations in the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug. Especially, Taketoshi lacks the disclosure of the step for substituting interlayer cations with hydrogen ions in the layered silicates.

There is no teaching or suggestion in Taketoshi to motivate one of ordinary skill in the art to modify the disclosed composition or method to produce the claimed hybrid wherein interlayer cations in the layered silicates are substituted with hydrogen ions to form ionic bonds between the layered silicates and the drug. Taketoshi does not even recognize the need for any improvement of the disclosed blended composition. Furthermore, Taketoshi fails to provide a reasonable expectation of success that one of ordinary skill in the art can modify the disclosed composition or the disclosed method to produce the claimed hybrid.

Instead, Taketoshi is limited to the blended composition wherein the drug is bound to the layered silicates via dipolar bonds which are much weaker bonds than ionic bonds.

In fact, Taketoshi teaches away from the claimed hybrid by teaching a step for removing hydrogen ions which are necessary for ionic bonding from the layered silicates to produce the blended composition. In paragraph [0005] of the English translation of Taketoshi provided by the Office, Taketoshi teaches that acid clay can be treated with alkali to be used as layered silicates for the blended composition. Acid clay contains hydrogen ions between the layers. However, during the alkali treatment (for example, with NaOH), hydrogen ions in the acid clay are extracted out of the layers because the hydrogen ions form water with hydroxide under the alkaline environment. As a result, the hydrogen ions are exchanged with cationic ions (for example, Na^+) in the layered silicates. That is, in the layered silicates of Taketoshi, hydrogen ions which are necessary for ionic bonds are replaced with cationic ions.

Therefore, Applicants respectfully submit that no *prima facie* case of obviousness has been established in this rejection.

Furthermore, since an ionic bond is much stronger than a dipolar bond in bonding force, the claimed hybrid wherein the layered silicates form ionic bonds with the drug results in an amorphous structure with superior stability in comparison with the blended composition disclosed in Taketoshi.

In light of the foregoing, Applicants submit that all outstanding rejections have been overcome, and the instant application is in condition for allowance. Thus, Applicants respectfully request early allowance of the instant application. The Commissioner is hereby authorized to charge any fees or credit any overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

By: _____

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